JUN 11 2008

K080180

510(k) Summary

Retinal Functional Imager 3000 (RFI 3000)

Date: June 4, 2008

Submitter's Name:

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Trade Name:

Retinal Functional Imager (RFI)

Classification Name:

Camera, Ophthalmic, AC Powered

Classification:

Classification	Primary	Secondary
Product Code:	HKI	HLI
Class:	II	II
Regulation Number	21 CFR 886.1120	21 CFR 886.1570
Regulation Name	Ophthalmic Camera	Ophthalmoscope

Predicate device:

Retinal Functional Imager (RFI) – cleared under 510(k) no. K062416

Description of Modification

The Retinal Functional Imager (RFI), cleared under 510(k) number K062416, was based on the RC-XV3 Fundus Camera manufactured by KOWA, Japan.

The modified RFI is based on the TRC-50DX Fundus Camera, manufactured by Topcon, Japan. The modification was introduced for commercial reasons only.

This user manual was revised to incorporate this modification (see attachment 4.1)

Substantial Equivalence:

The modified RFI is considered to be substantially equivalent to its predicate device, Retinal Functional Imager (RFI), cleared under **K062416**, without raising new safety and/or effectiveness issues.

Both devices are ophthalmic imaging management systems intended to capture, display, and store images of the retina to aid in diagnosing or monitoring diseases of the retina that may be observed and photographed.

Device Description:

The modified RFI, like the cleared RFI, is a mydriatic fundus imaging camera intended for taking red-free images. The modified RFI, as the cleared device, comprises of the following sub-assemblies:

- An optical system for illuminating and imaging the retina. The optical imaging includes a stroboscopic light source for sequential rapid imaging of the retina.
- A high resolution CCD camera.
- An electronic unit for driving the light source.
- A software package for operating the system, controlling the illumination, grabbing the images, data browsing and data analysis.

The device is also capable of using 35 mm film or using a digital camera similar to the predicate devices. Visible light is used for observation. Alignment and focusing is manual via the fundus camera controls.

Under red-free imaging, the modified RFI provides, through a series of multiple flashes, the ability to observe and register the blood flow velocity and path of motion.

Intended Use

The modified RFI, as the cleared device, is intended to observe, capture, display, and store images of patients' fundus (retina) under mydriatic conditions to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

The modified RFI, as the cleared device, provides information of blood flow (velocity) and path of flow in retinal vessels, but repeatability and trueness of the retinal blood flow velocity measurement has not been established clinically

The Retinal Functional Imager Technology

No changes were introduced in the device technology.

The Retinal Functional Imager (RFI) is a mydriatic fundus camera designed to take retinal images using a standard high resolution digital camera mounted on a conventional fundus camera and a stroboscopic light source. The images can be taken at high frame rates. To facilitate this imaging frame rate, the flash illumination system of the fundus camera has been modified to permit the delivery of strobe flashes at the camera's full frame rate in a fixed train of discharges. This extension of normal fundus camera capabilities allows new information to be obtained from the retina by extracting reflectance changes due to the motion of red blood cells through the blood circulation of the retina between images. The software is able to map the blood flow through blood vessels in the eye and determine the velocity of the flow by tracking the motion of the blood cells, taking into account various control factors.

The fundus camera has a manufacturer-rated magnification specification different for each available magnification setting. The digital camera demagnification power and sensor size give a calibration of digital camera pixels to actual microns on the retina and is used in the determination of blood flow velocity.

RFI Software - The software for the RFI is comprised of a Grab and Browse module. The Grab module is responsible for acquiring and saving raw image data to a disk. The Browse module provides a user interface for entering patient data and selecting the mode in which Grab will operate; it also allows the operator to review the acquired data before continuing with data grab operations. Additional embedded software provides the Grab module with hardware state control and monitoring services.

Performance Testing

A Risk Analysis was used to assess the impact of the modification on the device and its components as well as the results of the analysis;

Based on the Risk Analysis for the modified RFI device (see attachment 5.1), we have identified a need to verify the potential hazard associated with the radiation level of the modified device.

The modified device was found to have lower radiation level, due to the use of a narrower band-pass filter, and to meet the requirement of ISO 15004-2:2007, regarding exposure threshold limits (see attachment 5.2).

Bench testing were conducted on model RFI using a model eye simulation by fixed flow rates of human blood through a pipette of diameter 80 micron inner diameter.

Bench repeatability (standard deviation of repeated measurements under identical conditions) and accuracy (measured versus calculated results) of the retinal blood flow velocity (RBFV) measurements were evaluated based on model eye simulation using fixed flow rates of human blood through a pipette of diameter 80 micron inner diameter. Repeated (6-8) RFI retinal blood flow velocity measurements were obtained at each of six flow rates yielding calculated velocities ranging from 0.61 to 9.06 mm/sec. Bench variability increased as velocity increased, ranging from 0.13 mm/sec at mean RFI velocity 0.68 mm/sec to 1.22 mm/sec at mean RFI velocity 9.65 mm/sec. Mean differences between the RFI measured velocity and calculated velocity (RFI minus calculated) were all positive and ranged from 0.04 mm/sec at calculated velocity 1.21 mm/sec to 0.59 mm/sec at calculated velocity 9.06 mm/sec.

The average ratio between the expected and measured velocity is 1.07 and data obtained suggest that the velocity determined by the RFI is slightly higher (6.5%) than the actual but highly correlated. The linear regression fit is $Y=1.07X+0.064$ and the square of the correlation coefficient is 0.99.

The results of the bench repeatability and trueness study are provided below:

Table 1 - Bench Repeatability of Velocity Measurements

Number of repeated measurements	Mean RFI Velocity (mm/sec)	Standard Deviation (SD)	%CV (SD/mean)
6	9.65	1 .22	12.6%
6	6.57	0.72	11.0%
7	3.49	0.29	8.3%
6	2.53	0.23	9.1%
8	1.25	0. 16	12.8%
8	0.68	0 .13	19.1%

Table 2 - Bench Accuracy: Calculated Velocity versus RFI Velocity

Mean Calculated velocity	Mean RFI measured velocity	Difference = RFI minus calculated	% Difference = difference/calculated
9.06	9.65	0.59	6.5%
6.07	6.57	0.50	8.2%
3.04	3.49	0.45	14.8%
2.33	2.53	0.20	8.6%
1.21	1.25	0.04	3.3%
0.61	0.68	0.07	11.5%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optical Imaging, Ltd.
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JUN 11 2008

Re: K080180
Trade/Device Name: Retinal Function Imager (RFI) 3000
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: June 4, 2008
Received: June 4, 2008

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K080180

Device Name: Retinal Functional Imager (RFI)

Indications for Use: The Retinal Functional Imager (RFI) is intended to observe, capture, display, and store images of patients' fundus (retina) under mydriatic conditions to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

Prescription Use ___X___ (21 C.F.R. § 801.109 subpart D) OR Over the Counter Use_____ (21 C.F.R. § 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6/10/2008

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K080180